

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PURDUE NEUROSCIENCE COMPANY,
One Stamford Forum,
201 Tresser Boulevard
Stamford, Connecticut 06901-3431

Plaintiff,

v.

NEWRON PHARMACEUTICALS, S.p.A.,
Via R. Lepetit 34,
I-21040 Gerenzano, Italy

Defendant.

Civil Action No.:

Judge:

COMPLAINT UNDER 35 U.S.C. § 146

Plaintiff Purdue Neuroscience Company, through its undersigned attorneys, as and for its Complaint against Defendant Newron Pharmaceuticals, S.p.A., alleges as follows:

NATURE OF ACTION

1. This is an action under 35 U.S.C. § 146 to review a decision of the Board of Patent Appeals and Interferences (hereinafter "the Board") of the United States Patent and Trademark Office (hereinafter "the PTO") in a patent interference. Specifically, this action seeks review of "Decision -- Preliminary Motions -- Bd. R. 125" (Paper 84) (hereinafter "Decision on Preliminary Motions"), dated January 12, 2007, and "Judgment -- Preliminary Motions -- Bd. R. 127" (Paper 86) (hereinafter "Judgment"), dated January 12, 2007, entered by the Board in Patent Interference No. 105,394 ("the '394 interference"). Pursuant to 35 U.S.C. § 146 and 37 C.F.R. §

1.304, the time period for filing a civil action for remedy regarding these determinations ends on March 13, 2007. This Complaint is timely filed.

THE PARTIES

2. Plaintiff Purdue Neuroscience Company (hereinafter "Purdue Neuroscience") is a partnership having its principal place of business at One Stamford Forum, 201 Tresser Boulevard, Stamford, Connecticut 06901-3431.

3. Upon information and belief, Defendant, Newron Pharmaceuticals, S.p.A. (hereinafter "Newron"), is an Italian corporation, having a principal place of business at Via R. Lepetit 34, I-21040 Gerenzano, Italy.

JURISDICTION AND VENUE

4. This Court has jurisdiction over this action under 28 U.S.C. §§ 1331 and 1338(a) and under 35 U.S.C. § 146.

5. Venue is proper in this district under 28 U.S.C. § 1391(d) and 35 U.S.C. § 146.

PROCEDURAL BACKGROUND OF THE PATENT INTERFERENCE

6. Purdue Neuroscience is the owner of the entire right, title and interest in and to U.S. Appl. No. 10/429,764 ("the '764 application"), which is a patent application seeking to reissue U.S. Patent No. 6,479,484 B1, issued on November 12, 2002, entitled "Substituted 2-Aminoacetamides and the Use Thereof." The named inventors of this application are Nancy C. Lan, Yan Wang and Sui Xiong Cai (collectively referred to as "Lan").

7. On information and belief, Newron is the owner of the entire right, title and interest in and to U.S. Patent No. 6,306,903 B1 ("the '903 patent"), issued on October 23, 2001, entitled "Alpha-Aminoamide Derivatives Useful as Analgesic Agents." The named inventors of

this patent are Paolo Pevarello, Mario Varasi, Patricia Salvati and Claes Post (collectively referred to as "Pevarello").

8. On January 9, 2006, the Board issued "Declaration-Bd. R. 203(d)" (Paper 1) declaring and instituting the '394 Interference between the Lan '764 application and the Pevarello '903 patent, based on the subject matter defined by a single count, Count 1.

9. On March 23, 2006, the Board issued "Redeclaration - Bd. R. 203(c)" (Paper 32) (hereinafter "Redeclaration"), redeclaring the '394 Interference between the Lan '764 application and the Pevarello '903 patent solely to add Lan claims 32 and 33 to the interference. In the Redeclaration, the Board held that the claims of the parties corresponding to Count 1 of the '394 interference are claims 1-6 and 8-33 of the Lan '764 application and claims 1-12 of the Pevarello '903 patent. The subject matter of Count 1, Pevarello's claim correspondence and the parties' accorded priority benefit dates remained the same as that set forth in "Declaration-Bd. R. 203(d)" (Paper 1).

10. Count 1, the sole count in the '394 Interference, states as follows: A method according to Claim 1 of U.S. Application 10/429,764 or Claim 1 of U.S. Patent 6,306,903.

11. The parties filed seven motions for the Board to consider. Pevarello filed five substantive motions as well as a miscellaneous motion to exclude evidence, while Lan filed a miscellaneous motion to exclude evidence. Generally, Pevarello filed substantive motions: (i) to substitute a proposed new count for Count 1; (ii) to be accorded the benefit of an earlier filed application; (iii) for judgment that all of Lan's involved claims, claims 1-6 and 8-33, are unpatentable to Lan for lack of enablement under 35 U.S.C. § 112, ¶1 and for obviousness under 35 U.S.C. § 103; (iv) to deny Lan benefit of Lan's earliest filed application; and (v) for judgment

that Lan claims 1, 2, 5, 6, 8-10, 13 and 20-33 are unpatentable to Lan for lack of a written description under 35 U.S.C. § 112, ¶1.

12. The Oral Hearing occurred on November 8, 2006. The Board rendered its January 12, 2007 Decision on Preliminary Motions, granting only that portion of Pevarello Substantive Motion 3 (hereinafter "PSM3") requesting that the Board find that all of the involved claims of Lan's application are unpatentable for lack of enablement under 35 U.S.C. § 112, ¶1. The Board dismissed the rest of PSM3 as moot to the extent it requested that Lan's involved claims be held unpatentable as obvious under 35 U.S.C. § 103. The Board also dismissed Pevarello's remaining motions as moot in light of the Board's determination that all of Lan's claims are unpatentable. Additionally, the Board denied Lan's Motion to Exclude Evidence. On January 12, 2007, the Board issued its Judgment ordering that priority of invention as to Count 1 be awarded against Lan and further ordering that Lan is not entitled to claims 1-6 and 8-33 of the Lan '764 application, all of which correspond to Count 1.

DISSATISFACTION WITH THE BOARD'S DECISION

13. Purdue Neuroscience, as a real party in interest, is dissatisfied with the Board's determinations in the '394 Interference. The rulings and judgment of the Board in its January 12, 2007 Decision on Preliminary Motions and in its Judgment in the '394 Interference were erroneous. Purdue Neuroscience is entitled to a judgment and decision correcting the erroneous judgment and rulings of the Board, based on the record before the Board and any additional evidence that Purdue Neuroscience may introduce in this action.

14. The Board's decisions were erroneous both in fact and law. The Board overlooked or misapprehended significant evidence on the issue of enablement presented by Lan. Additionally, in determining whether the specification provides an enabling disclosure to a

person of ordinary skill in the art, the Board misapprehended the need for testimony from a person with first hand knowledge of the assay described in Lan's specification. Furthermore, the Board erroneously relied on the Federal Circuit's decision in *Rasmusson v. SmithKline Beecham Corp.*, 413 F.3d 1318 (Fed Cir. 2005) (hereinafter "*Rasmusson*"), overlooking material facts distinguishing the '394 Interference from *Rasmusson*. Thus, the Board erroneously found Lan's involved claims unpatentable for lack of enablement in its Decision on Preliminary Motions. The Board also erroneously denied Lan's Motion to Exclude. In particular, the Board erred by not excluding Dr. Stephen Waxman's testimony in view of the improper coaching by counsel for Pevarello that was found by the Board in its separate Memorandum Opinion and Order (Paper 85), dated January 12, 2007, which formed a part of the Board's Decision on Preliminary Motions. For at least these reasons, the Board erroneously found the involved claims of Lan's application unpatentable for lack of enablement.

PRAYER FOR RELIEF

WHEREFORE, Purdue Neuroscience prays for a judgment:

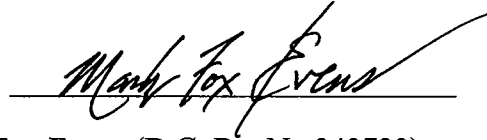
- A. Reversing and vacating the Board's Decision on Preliminary Motions, dated January 12, 2007, and Judgment, dated January 12, 2007, in the '394 Interference;
- B. Finding the involved claims of Lan's '764 application patentable and not invalid under 35 U.S.C. § 112, ¶1;
- C. Remanding the '394 interference to the Board for a determination of priority of the subject matter of Count 1 and for a determination of Lan's motion that all of Pevarello's involved claims are unpatentable under 35 U.S.C. § 102(e);
- D. Awarding costs and reasonable attorney's fees in favor of Purdue Neuroscience;
and
- E. Awarding Purdue Neuroscience any further relief that this Court may deem appropriate.

Respectfully submitted,

PURDUE NEUROSCIENCE COMPANY

Date: March 12, 2007

By:

A handwritten signature in black ink, reading "Mark Fox Evens", is written over a horizontal line.

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